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Date April 26, 2002 Patent No. 6,419,958

I hereby certify that, on the date indicated above, I deposited this paper or fee with the U.S. Postal Service and that it was addressed for delivery to the Assistant Commissioner for Patents, Washington, DC 20231 by "Express Mail Post Office to Addressee" service.

Sandra Stocklinski

Name (Print)

Sandra Stocklinski

Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: ROSENGART)

)

Group Art Unit: 3738

Application No.: 10/060,958)

)

Examiner: Unassigned

Filed: January 30, 2002)

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For: METHOD AND APPARATUS FOR PERFORMING AN ANASTAMOSIS

PRELIMINARY AMENDMENT

The Assistant Commissioner for Patents
Washington, D.C. 20231

April 26, 2002

Sir:

Prior to examination of the above-identified application on the merits, the applicant respectfully requests that the application be amended as follows:

IN THE SPECIFICATION:

Please substitute the following amended parts of the specification as indicated in the above-identified application. (A version of the amended specification with markings to show the changes made is also attached.)

At page 9, lines 13-20, please replace the paragraph with the following amended paragraph:

--With reference to the figures, the present invention includes first elongated instrument 15, Fig. 1, inserted into a patient's vascular system. First elongated instrument 15 may include

aortic catheter 17 and aortic guide device 20 that can be advanced towards heart 10 and into and within the aorta to a desired position. In the preferred embodiment, aortic guide device 20 is an aortic guide wire. The catheters and guide devices can be commercially available tools. The reference to "aortic" for aortic catheter is to better explain the location of use of the catheter and the size and shape requirements that would preferably be used in view of its location of use. This would be true to the other terms preceding "guide wire" and "catheter" and the like.--

At page 10, lines 9-19, please replace the paragraph with the following amended paragraph:

--The second elongated instrument that is insertable into the patient's vascular system includes a coronary catheter and a coronary guide device. The coronary guide device, which is preferably a flexible coronary guide wire is directed towards the coronary artery to preferably perforate the coronary artery at a predetermined location and can protrude outside of the coronary artery. The coronary guide device may include at least one radio-opaque marker to determine its location within the coronary artery. The second elongated instrument may optionally include at least one hemostatic object 50, Fig. 3, to block blood flow. Hemostatic object 50 is preferably a balloon. Hemostatic object 50 may include a first channel that prevents blood flow blockage by directing the blood flow from one side of the hemostatic object to the second side of the hemostatic object. The guide device can perforate the coronary artery or be used to guide an aperture-creating device.--

At page 12, lines 13-15, please replace the paragraph with the following amended paragraph:

--Fig. 4 is a cross-sectional schematic of one example of a second elongated instrument illustrating second elongated instrument 30, T-shaped perforating guide 45, coronary guide wire 35 (which guides the second elongated instrument to the coronary artery) and first channel 40.--

At page 15, lines 7-9, please replace the paragraph with the following amended paragraph:

--In the preferred embodiment of the present invention, the thoracic catheter of the third elongated instrument may include hemostatic object 130, Fig. 10, sheath 150, concave curvature 135 to evert graft edge 145 outwards, and a step-off 140 to limit the advancement of a dilator.--

At page 18, lines 19-23, please replace the paragraph with the following amended paragraph:

--A sheath, a coupler and a conical shaped-device are preferably attached at each end of graft 360 (proximal end and distal end). Additionally, the third elongated instrument, e.g., thoracic catheter 305, Fig. 12, preferably with hemostatic object 320 are placed into graft 360. In one example, elongated instrument 300, Fig. 12, illustrates sheath 310, coupler 340 and conical-shaped device 330 at the end of graft 360 closer to the coronary artery.--

At page 21, lines 14-23 and page 22, lines 1-2, please replace the paragraph with the following amended paragraph:

--As discussed above, using the aortic guide device, the aorta catheter with balloon (e.g., aortic catheter 17 and balloon 400, Fig. 13) can be inserted through the femoral artery of the patient and pass through the aorta and through the aortic aperture and then the thoracic aperture to the exterior of the patient. The distal end of the coronary guide device or the T-shaped

perforating guide device can then be inserted into the aorta catheter and fed completely through to the femoral artery or other entry point of the patient such that the distal end of the coronary guide device or the T-shaped perforating guide device is visible at this location. In the alternative, if the length of the graft is long enough to be visible or to be physically outside of the thoracic aperture, the aorta catheter preferably with a balloon can be inserted into the unattached end of the graft without the need to feed the coronary guide device or T-shaped perforating guide device into the aorta catheter. This would be a more simplified approach if it is physically possible due to the length of the graft. Either approach can be used depending upon the circumstances and the length of the graft.--

At page 22, lines 18-23, and page 23, lines 1-9, please replace the paragraph with the following amended paragraph:

--The aortic catheter with balloon is preferably inserted through the aperture of the second conical-shaped device. Once the conical-shaped device is holding the compressed ring, the balloon can be expanded to press against the graft and/or coupler, which permits the ability to maneuver and navigate the graft to the aorta aperture. Fig. 14 illustrates an example wherein catheter 17 with balloon 400 is inserted through aperture 430. Additionally, compressed ring 420 is inside the conical-shaped device and balloon 400 is expanded to press against graft 360 and/or coupler 410. Once at the aperture site, and after traction with the balloon on the coupler has caused the conical-shaped device to enter through the aortic aperture, the balloon can be deflated slightly in order to avoid pressing against the graft wall while having a sufficient diameter to press up against the conical-shaped device and to remove the conical-shaped device from the

compressed ring. This procedure permits the ring to release to its normal diameter and attach onto the wall surrounding the aorta aperture, and thereby attaching the proximal end of the graft onto the aorta wall. The aortic catheter with balloon and the conical-shaped device can then be retrieved from this area by retracting the coronary guide device (if used) or preferably T-shaped perforating guide device 45 (if used) and aortic catheter with balloon through the original entry point of the femoral artery at the leg site. Again, bio-adhesive or other sealing means can be used to further ensure a fluid tight connection between the graft and the wall surrounding the aorta aperture.--

IN THE CLAIMS:

Please substitute the following claims as indicated in the above-identified application. (A version of the amended claims with markings to show the changes made is also attached).

9. (Amended) The graft delivery system of claim 8, wherein said first hemostatic object comprises a first channel, wherein said first channel directs said blood flow from one side of said first hemostatic object blocking said blood flow to a second side of said first hemostatic object.

27. (Amended) The graft delivery system of claim 26, wherein said compressible ring is made of Nitinol, stainless steel, titanium, polyimide, super-elastic alloys, or combinations thereof.

43. (Amended) The method of claim 42, further comprising releasing said coupler from within said conical-shaped device to attach said coronary artery to said graft.

53. (Amended) The method of claim 41, wherein said third elongated instrument is a thoracic catheter having a hemostatic object and is inserted into said graft at exterior of said patient's thoracic region and wherein said thoracic catheter is used to navigate said graft to said coronary aperture.

74. (Amended) The graft delivery system of claim 67, wherein said coupler comprises a compressible ring that is capable of forming back to its original shape.

77. (Amended) The graft delivery system of claim 67, further comprising a sheath over said coupler.

78. (Amended) A method for using a mammary artery as a graft using said graft delivery system of claim 66 comprising:

- a) creating a thoracic aperture;
- b) inserting said mammary guide device into said patient's vascular system;
- c) cutting the mammary artery to create a severed end thereof;
- d) navigating the distal end of said mammary guide device to protrude out of the severed end of said mammary artery;
- e) inserting said second elongated instrument into said patient's vascular system;
- f) navigating said second elongated instrument to a pre-determined location in said coronary artery;
- g) protruding said coronary guide device to the outside of said coronary artery, thereby creating a coronary aperture;

h) retrieving said mammary guide device and extracting said mammary guide device with said retrieving device and retrieving said coronary guide device and extracting said coronary guide device with said retrieving device and from said thoracic region of said patient to outside of said thoracic region of said patient;

i) inserting a thoracic elongated instrument into said patient by way of the thoracic aperture and navigating the distal end of the thoracic elongated instrument through the severed end of the mammary artery such that the distal end of the thoracic elongated instrument exits through the insertion point of the mammary guide device;

j) removing the mammary guide device from the patient and inserting the distal end of the coronary guide device into the proximal end of the thoracic elongated instrument and navigating the distal end of the coronary guide device such that the distal end of the coronary guide device exits out the patient through the insertion point of the mammary guide device of the patient; and

k) attaching said severed end of said mammary artery to said coronary aperture to make a fluid tight connection.

81. (Amended) The method of claim 78, further comprising inserting a conical-shaped device in said severed end of said mammary artery, wherein said conical-shaped device includes a coupler.

87. (Amended) The method of claim 78, wherein said mammary catheter further comprises a balloon at one end to hold said severed end of said mammary artery and wherein said mammary catheter and said balloon are attached to said severed end of said mammary artery.

91. (Amended) The method of claim 79, wherein said coupler is compressed within a conical-shaped device outside of thoracic region of said patient, and wherein said conical-shaped device is delivered to said severed end of said mammary artery by said third elongated instrument.

92. (Amended) The method of claim 79, wherein said coupler is a compressible ring.

94. (Amended) The method of claim 90, wherein said coupler at said severed end of mammary artery is attached to said mammary artery by withdrawing a sheath and expanding a hemostatic object within said thoracic catheter.

95. (Amended) The method of claim 79, wherein said coupler at said severed end of said mammary artery is released from within said conical-shaped device by advancing the conical-shaped device relative to the position of the coupler, which is maintained by inflation of a balloon component of said third elongated instrument.

96. (Amended) The method of claim 78, further comprising inserting a fiber optic light/video camera system through said thoracic aperture.

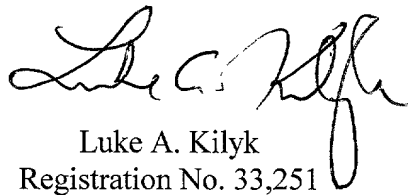
Preliminary Amendment
U.S. Patent Application No. 10/060,958

REMARKS

No questions of new matter are raised by the above amendment. Entry of the above amendment is therefore respectfully requested.

If there are any fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such extension is requested and should also be charged to our Deposit Account.

Respectfully submitted,



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**VERSION WITH MARKINGS TO SHOW CHANGES MADE
IN THE SPECIFICATION:**

Replacement paragraph on page 9, lines 13-20.

With reference to the figures, the present invention includes first elongated instrument 15, Fig. 1, inserted into a patient's vascular system. First elongated instrument 15 may include aortic catheter 17 and aortic guide device 20 that can be advanced towards heart 10 and into and within the aorta to a desired position. In the preferred embodiment, aortic guide device 20 is an aortic guide wire. The catheters and guide devices can be commercially available tools. The reference to "aortic" for aortic catheter is to better explain the location of use of the catheter and the size and shape requirements that would preferably be used in view of its location of use. This would be true to the other terms preceding "guide wire" and "catheter" and the like.

Replacement paragraph on page 10, lines 9-19.

The second elongated instrument that is insertable into the patient's vascular system includes a coronary catheter and a coronary guide device. The coronary guide device, which is preferably a flexible coronary guide wire is directed towards the coronary artery to preferably perforate the coronary artery at a predetermined location and can protrude outside of the coronary artery. The coronary guide device may include at least one radio-opaque marker to determine its location within the coronary artery. The second elongated instrument may optionally include at least one hemostatic object 50, Fig. 3, to block blood flow. Hemostatic object 50 is preferably a balloon. Hemostatic object 50 may include a first channel that prevents blood flow blockage by directing the blood flow from one side of the hemostatic object to the second side of the

hemostatic object. The guide device can perforate the coronary artery or be used to guide an aperture-creating device.

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Replacement paragraph on page 15, lines 7-9.

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Replacement paragraph on page 18, lines 19-23.

A sheath, a coupler and a conical shaped-device are preferably attached at each end of graft 360 (proximal end and distal end). Additionally, the third elongated instrument, e.g., thoracic catheter 305, Fig. 12, preferably with hemostatic object 320 are placed into graft 360. In one example, elongated instrument 300, Fig. 12, illustrates sheath 310, coupler 340 and conical-shaped device 330 at the end of graft 360 [110] closer to the coronary artery.

Replacement paragraph on page 21, lines 14-23 and page 22, lines 1-2.

As discussed above, using the aortic guide device, the aorta catheter with balloon (e.g., aortic catheter 17 and balloon 400, Fig. 13) can be inserted through the femoral artery of the patient and pass through the aorta and through the aortic aperture and then the thoracic aperture

to the exterior of the patient. The distal end of the coronary guide device or the T-shaped perforating guide device can then be inserted into the aorta catheter and fed completely through to the femoral artery or other entry point of the patient such that the distal end of the coronary guide device or the T-shaped perforating guide device is visible at this location. In the alternative, if the length of the graft is long enough to be visible or to be physically outside of the thoracic aperture, the aorta catheter preferably with a balloon can be inserted into the unattached end of the graft without the need to feed the coronary guide device or T-shaped perforating guide device into the aorta catheter. This would be a more simplified approach if it is physically possible due to the length of the graft. Either approach can be used depending upon the circumstances and the length of the graft.

Replacement paragraph on page 22, lines 18-23, and page 23, lines 1-9.

The aortic catheter with balloon is preferably inserted through the aperture of the second conical-shaped device. Once the conical-shaped device is holding the compressed ring, the balloon can be expanded to press against the graft and/or coupler, which permits the ability to maneuver and navigate the graft to the aorta aperture. Fig. 14 illustrates an example wherein catheter 17 with balloon 400 is inserted through aperture 430. Additionally, compressed ring 420 is inside the conical-shaped device and balloon 400 is expanded to press against graft 360 and/or coupler 410. Once at the aperture site, and after traction with the balloon on the coupler has caused the conical-shaped device to enter through the aortic aperture, the balloon can be deflated slightly in order to avoid pressing against the graft wall while having a sufficient diameter to press up against the conical-shaped device and to remove the conical-shaped device from the

compressed ring. This procedure permits the ring to release to its normal diameter and attach onto the wall surrounding the aorta aperture, and thereby attaching the proximal end of the graft onto the aorta wall. The aortic catheter with balloon and the conical-shaped device can then be retrieved from this area by retracting the coronary guide device (if used) or preferably T-shaped perforating guide device 45 (if used) and aortic catheter with balloon through the original entry point of the femoral artery at the leg site. Again, bio-adhesive or other sealing means can be used to further ensure a fluid tight connection between the graft and the wall surrounding the aorta aperture.

**VERSION WITH MARKINGS TO SHOW CHANGES MADE
IN THE CLAIMS:**

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27. (Amended) The graft delivery system of claim 26, wherein said compressible ring is made of Nitinol, stainless steel, titanium, polyimide, super-elastic alloys, or combinations thereof.

43. (Amended) The method of claim 42, further comprising releasing [a] said coupler from within said conical-shaped device to attach said coronary artery to said graft.

53. (Amended) The method of claim 41, wherein said third elongated instrument is a thoracic catheter having a hemostatic object and is inserted into [the] said graft at exterior of said

patient's thoracic region and wherein said thoracic catheter is used to navigate said graft to said coronary aperture.

74. (Amended) The graft delivery system of claim [66] 67, wherein said coupler comprises a compressible ring that is capable of forming back to its original shape.

77. (Amended) The graft delivery system of claim [66] 67, further comprising a sheath over said coupler.

78. (Amended) A method for using a mammary artery as a graft using said graft delivery system of claim [69] 66 comprising:

- a) creating a thoracic aperture;
- b) inserting said mammary guide device into said patient's vascular system;
- c) cutting the mammary artery to create a severed end thereof;
- d) navigating the distal end of said mammary guide device to protrude out of the severed end of said mammary artery;
- e) inserting said second elongated instrument into said patient's vascular system;
- f) navigating said second elongated instrument to a pre-determined location in said coronary artery;
- g) protruding said coronary guide device to the outside of said coronary artery, thereby creating a coronary aperture;
- h) retrieving said mammary guide device and extracting said mammary guide device with said retrieving device and retrieving said coronary guide device and extracting said coronary

guide device with said retrieving device and from said thoracic region of said patient to outside of said thoracic region of said patient;

i) inserting a thoracic elongated instrument into said patient by way of the thoracic aperture and navigating the distal end of the thoracic elongated instrument through the severed end of the mammary artery such that the distal end of the thoracic elongated instrument exits through the insertion point of the mammary guide device;

j) removing the mammary guide device from the patient and inserting the distal end of the coronary guide device into the proximal end of the thoracic elongated instrument and navigating the distal end of the coronary guide device such that the distal end of the coronary guide device exits out the patient through the insertion point of the mammary guide device of the patient; and

k) attaching said severed end of said mammary artery to said coronary aperture to make a fluid tight connection.

81. (Amended) The method of claim 78, further comprising inserting a conical-shaped device in said severed end of said mammary artery, wherein said conical-shaped device includes [said] a coupler.

87. (Amended) The method of claim 78, wherein said [thoracic] mammary catheter further comprises a balloon at one end to hold said severed end of said mammary artery and wherein said [thoracic] mammary catheter and said balloon are attached to said severed end of said mammary artery.

91. (Amended) The method of claim 79, wherein said coupler is compressed within a conical-shaped device outside of thoracic region of said patient, and wherein said conical-shaped device is delivered to said severed end of said mammary artery by said third elongated instrument.

92. (Amended) The method of claim [78] 79, wherein said coupler is a compressible ring.

94. (Amended) The method of claim [78] 90, wherein said coupler at said severed end of mammary artery is attached to said mammary artery by withdrawing a sheath and expanding a hemostatic object within said thoracic catheter.

95. (Amended) The method of claim [92] 79, wherein said coupler at said severed end of said mammary artery is released from within said conical-shaped device by [by] advancing the conical-shaped device relative to the position of the coupler, which is maintained by inflation of a balloon component of said third elongated instrument.

96. (Amended) The method of claim [79] 78, further comprising inserting a fiber optic light/video camera system through said thoracic aperture.